CERTIFICATE OF TRANSMITTAL

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[name of person signing]

PATENT

Applicant:	Donald E. Bobo, Jr.
Serial No.:	10/021,132
Filed:	October 29, 2001
Title:	METHODS AND APPARATUS FOR PROVIDING MEDICAMENT TO TISSUE
Examiner:	Shay, David M.
Group Art Unit:	3735
Confirmation No.:	2468
Atty. Docket No.:	CVG-5637

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF AND AMENDED APPEAL BRIEF UNDER 37 CFR 41.37

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Response to Notification of Non-Compliant Appeal Brief and Amended Appeal Brief Under 37 CFR 41.37 is being filed in response to the Notification of Non-Compliant Appeal Brief mailed November 27, 2007 in the above-identified patent application, in which the Examiner indicated that:

I. The brief does not contain the items required under 37 CFR 41,37(c), or the items are not under the proper heading or in the proper order;

II. (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to

each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)); and

III. Other (including any explanation in support of the above-items): The Brief does not, in the Summary of Claimed Subject Matter, refer to the specification by page and line number.

The Summary of Claimed Subject Matter now refers to the originally filed specification by page and line number for all pending claims. Therefore, it is now believed that this Amended Appeal Brief is now in compliance with 37 CFR 41,37(c).

In response to the Final Office Action mailed February 22, 2007, please consider the Appeal Brief contained herein. It is believed that this Appeal Brief addresses all outstanding issues; that entry of this Appeal Brief is proper; and that the preparation and mailing of an Examiner's Answer is now in order.

The fee for filing of this Appeal Brief has been previously submitted.

REAL PARTY IN INTEREST

The real party in interest is Edwards Lifesciences Corporation, a California corporation having a place of business at One Edwards Way, Irvine, CA 92614-5686. Edwards Lifesciences Corporation is the Assignee of all rights in the application.

RELATED APPEALS AND INTERFERENCES

There are currently no appeals or interferences known to the appellant, the appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 36-44 are currently pending and of these claims, claims 36, 39 and 42 are independent. Claims 1-35 and 45 have been previously canceled. Claims 36-44 are rejected. Claims 36-44 are currently being appealed.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to final rejection. The claims as they are currently entered are presented in the Appendix of this document.

SUMMARY OF CLAIMED SUBJECT MATTER

Claims 36, 39 and 42 of the appealed claims 26-44 are independent and the remaining claims depend from one of these three claims.

In accordance with 37 C.F.R. 41.37(c)(1)(v) the subject matter of independent claims 36, 39 and 42 is concisely explained below. It is believed that none of these independent claims includes means plus function or step plus function wording.

The subject matter as defined in claim 36 involved in this appeal relates to a method for delivering medicament to tissue in a chamber of the heart with a delivery device while traversing a right atrium and sealably traversing an atrial septum (page 4 line 25 through page 5 line 4; page 39 lines 20-25)[1]. As shown in one example embodiment in FIG. 42a, the delivery device 300' comprises a deflated first balloon 316a and a deflated second balloon 316b in communication with at least one internal inflation lumen 318 (page 38 lines 20-22). The device 300' is advanced to a position proximate the area of interest, such as an atrial septum, and a hole 320 is formed in the tissue 308a (page 38 lines 22-23).

As shown in FIG. 42b, the distal portion of the device 300' and the deflated second balloon 316b is advanced therethrough (page 38 lines 23-24). Thereafter, the

[1] Paragraph numbers reflect those appearing in the application as published on May 1, 2003 as US 2003-0083607 A1. Page and line numbers reflect the application as originally filed.

first balloon 316a and the second balloon 316b are inflated, thereby supportively engaging the tissue 308a disposed therebetween (page 38 lines 24-26). Thereafter the device 300' is advanced to and engages tissue 308b (page 38 lines 26-27). As seen in FIG. 42c, a tissue ablating member 310 is positioned on the distal end of the device for creating a channel through the surface of the tissue 308b (page 38 line 30 through page 39 line 2). Once the channel is created, medicament is delivered to the channel, for example, through a port on the distal end of the device (page 38 lines 27-30).

The subject matter as defined in claim 37 involved in this appeal relates to the previously described subject matter of claim 36 and further includes a first balloon and a second balloon (page 38 lines 20-23). The atrial setum supportively engaged at the opening of the medicament delivery catheter by inflating the first balloon of the catheter on a proximal side of the opening and inflating the second balloon of the catheter on the distal side of the opening (page 38 line 23 through page 39 line 2).

The subject matter as defined in claim 38 involved in this appeal relates to the previously described subject matter of claim 37 and further recites that the atrial septum is received between the first balloon and the second balloon and supported by the inflated first balloon and second balloon (page 38 line 23 through page 39 line 2).

The subject matter as defined in claim 39 involved in this appeal relates to a method of delivering medicament to tissue while preventing medicament washout (page 3 lines 24-28). As seen in FIGS. 41a-41c, a delivery device 300' is advanced to a tissue surface so that the distal end of the delivery device 300' is proximate the tissue surface (page 38 lines 8-9).

As shown in FIG. 41a, the device 300' comprises at least one vacuum port 312' positioned radially about the tissue-engaging surface 306' and in communication at least one vacuum lumen 314' located within the device 300' to engage the tissue 308' (page 38 lines 5-8). The device is advanced to a position proximal the tissue 308 (page 38 lines 8-9). An external vacuum source (not shown) is activated and a vacuum force is

transmitted to the at least one vacuum port 312' through the vacuum lumen 314' (page 38 lines 9-10).

Thereafter, the device 300' is advance to engage the tissue 308, resulting in tissue 308 being retained and sealed by the device 300' (page 38 lines 11-12). The ablating member 310' may then be advanced into the tissue 308 to create a channel in the tissue 308 (page 38 lines 12-13). FIG. 41b shows the present invention retaining a portion of tissue 308' and advancing the ablating member 310' therein (page 38 lines 13-14). FIG. 41c shows the distal portion of the present invention comprising a tissue ablating member 310 positioned thereon and having four vacuum ports 312a-d positioned on the tissue-engaging surface 306 (page 38 lines 14-16). The medicament is then delivered into the channel and prevented from passing between the tissue-engaging surface 306 and the tissue 308 (page 5 lines 28-29; page 3 lines 24-28; page 38 lines 16-18).

The subject matter of claim 40 involved in this appeal relates to the previously discussed subject matter of claim 39 and further includes at least one vacuum port positioned radially about the tissue engaging surface and at least one vacuum lumen located within the catheter (Fig. 41a, page 38 lines 5-9).

The subject matter of claim 41 involved in this appeal relates to the previously discussed subject matter of claim 40 and further includes four vacuum ports (Fig. 41c, page 38 lines 16-18).

The subject matter as defined in claim 42 involved in this appeal relates to a method of delivering medicament to tissue while preventing medicament washout (page 3 lines 24-28).

As illustrated in FIG. 43a-43c, a distal end of the device 300' is advanced to the surface of tissue 308' (page 39 lines 7-8). The distal portion of the device 300' further comprises at least one sealing balloon 330 in communication with at least one internal inflation lumen 318' (page 39 lines 3-6). As shown in FIG. 43, the distal portion of device 300' is positioned proximate the tissue 308' (page 39 lines 7-8). The at least one sealing

balloon 330 is inflated and sealably engages the tissue 308' (page 39 lines 7-8). Thereafter, a tissue channel 332 is formed by advancing the ablating member 334 into the tissue 308' (page 39 lines 8-9). A medicament, for example an angiogenesis-inducing agent, may be applied through port 336 to the tissue 308' forming the channel 332 (page 39 lines 9-11). The at least one sealing balloon 330 prevents medicament washout by sealing the tissue channel 332 (page 39 lines 11-14).

The subject matter of claim 43 involved in this appeal relates to the previously discussed subject matter of claim 42 and further includes maintaining the inflated balloon against the tissue surface while the opening is formed (page 39 lines 6-9)

The subject matter of claim 44 involved in this appeal relates to the previously discussed subject matter of claim 42 and further includes maintaining the inflated balloon against the tissue opening while the medicament is delivered (page 39 lines 6-14).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. GROUND 1 – REJECTION OF CLAIMS 36-38 UNDER SECTION 112

The first ground of rejection to be reviewed on appeal is the Examiner's rejection of claims 36-38 under 35 U.S.C. Section 112, first paragraph. The Examiner contends that the specification does not support "supportively engaging the medicament delivery catheter with the atrial septum" as claimed in claim 36" as recited in these claims.

II. GROUND 2 – REJECTION OF CLAIMS 36-38 UNDER SECTION 112

The second ground of rejection to be reviewed on appeal is the Examiner's rejection of claims 36-38 under 35 U.S.C. Section 112, first paragraph. The Examiner contends that the specification does not support a "medicament delivery catheter".

III. GROUND 3 – REJECTION OF CLAIMS 42-44 UNDER SECTION 102

The third ground of rejection to be reviewed on appeal is the Examiner's rejection of Claims 42-44 under 35 U.S.C. Section 102(e) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. (*The Flaherty et al. Patent*).

IV. GROUND 4 – REJECTION OF CLAIMS 36-38 UNDER SECTION 103

Claims 36-38 are rejected under 35 U.S.C. Section 103(a) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. (*The Flaherty et al. Patent*) in combination with U.S. Patent No. 6,645,199 to Jenkins et al. (*The Jenkins et al. Patent*), U.S. Patent No. 6,161,543 to Cox et al. (*The Cox et al. Patent*) and U.S. Patent Application No. 2001/0049497 to Kalloo et al. (*The Kalloo et al. Publication*).

V. GROUND 5 – REJECTION OF CLAIMS 39 AND 40 UNDER SECTION 103

Claims 39 and 40 are rejected under 35 U.S.C. Section 103(a) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. (*The Flaherty et al. Patent*) in combination with U.S. Patent No. 6,645,199 to Jenkins et al. (*The Jenkins et al. Patent*), U.S. Patent No. 5,725,523 to Mueller (*The Mueller Patent).*

VI. GROUND 5 – REJECTION OF CLAIM 41 UNDER SECTION 103

Claim 41 is rejected under 35 U.S.C. Section 103(a) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. (*The Flaherty et al. Patent*) in combination with U.S. Patent No. 6,645,199 to Jenkins et al. (*The Jenkins et al. Patent*), U.S. Patent No. 5,725,523 to Mueller (*The Mueller Patent)* in further view of U.S. Patent No. 5,607,421 to Jeevanandam et al. (*The Jeevanandam et al. Patent*).

ARGUMENT

I. GROUND 1 – REJECTION OF CLAIMS 36-38 UNDER SECTION 112

The Examiner rejects claims 36-38 under 35 U.S.C. Section 112, first paragraph and contends that the specification does not support "supportively engaging the medicament delivery catheter with the atrial septum" as claimed in claim 36".

Section 2163.02 of the M.P.E.P. best describes the legal standards for a section 112, first paragraph rejection as follows:

> The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).
>
> Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show

> that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").
>
> The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. This conclusion will result in the rejection of the claims affected under 35 U.S.C.112, first paragraph - description requirement, or denial of the benefit of the filing date of a previously filed application, as appropriate.

As previously stated in the Amendment filed November 30, 2006, this language is no longer present in independent claim 36 (and thereby dependent claims 37-38). Claim 36 was amended to recite, in part, "supportively engaging the atrial septum at the opening with the medicament delivery catheter". Support for this recited language can be found in paragraph 0151 of the present Application (page 38, line 19-page 39, line 2; amended March 30, 2006) which states:

> [0152] An alternate embodiment of the present invention is illustrated in FIG. 42a-42c. As shown in FIG. 42a, the device 300' comprises a deflated first balloon 316a and a deflated second balloon 316b in communication with at least one internal inflation lumen 318. The device 300' is advanced to a position proximate the area of interest and a hole 320 is formed in the tissue 308a. As shown in FIG. 42b, the distal portion of the device 300' and the deflated second balloon 316b is advanced therethrough. **Thereafter, the first balloon 316a and the second balloon 316b are inflated, thereby supportively engaging the tissue 308a disposed therebetween.** Thereafter the device 300' is advanced to and engages tissue 308b. Those skilled in the art will appreciate the present embodiment may be used to isolate discrete portion of tissue or organs. **For example, as shown in FIG 42d, the present invention may be utilized to sealably traverse the atrial septum 326 and precisely ablate and inject medicament to an**

> **isolated chamber 328 of the heart.** FIG. 42c shows the distal portion of the present invention comprising a tissue ablating member 310 and having a first and second balloon 316a-b positioned thereon. [Emphasis added]

Since the specification and claim 36 recite nearly identical terms and language, it is believe that claim language of claims 36-38, and specifically the recited language "supportively engaging the atrial septum at the opening with the medicament delivery catheter" conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, that the applicant was in possession of the invention as now claimed. Therefore, it is submitted that these claims are properly supported under Section 112, first paragraph and the legal standards summarized in Section 2163.02 of the M.P.E.P.. It is therefore requested that this rejection of claims 36-38 be withdrawn.

II. GROUND 2 – REJECTION OF CLAIMS 36-38 UNDER SECTION 112

The second ground of rejection to be reviewed on appeal is the Examiner's rejection of claims 36-38 under 35 U.S.C. Section 112, first paragraph. The Examiner contends that the specification does not support a "medicament delivery catheter".

As previously reproduced in the discussion of the first grounds of rejection, Section 2163.02 of the M.P.E.P. best describes the legal standards for a section 112, first paragraph rejection. For example, that "the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed."

Numerous embodiments of the invention described in the present Application provide support for the device being in catheter form. For example, paragraph 0087 (page 14, line 15), "...handpiece 54 may be a flexible catheter..."; paragraph 0090 (page 15, line 26), "...handpiece 54 such as a catheter..."; paragraph 0113 (page 23, line 30), "When handpiece 54 is configured as a catheter..."; paragraph 0140 (page 34, lines 7-8), "System 230 includes an ablating and injecting device 232 received within a catheter 234..."; paragraph 0141 (page 34, lines 20-21), "...guiding the ablating and injecting device 232 and catheter 234..."; and paragraph 0153 (page 39, lines 18-19),

"...the present embodiment permits catheter-based delivery of the ablation and injection system..." to name just a few examples.

Since the specification and claim 36 clearly describe the use of the present invention as a "medicament delivery catheter" it is submitted that claims 36-38 convey with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. Therefore, these claims are properly supported under Section 112, first paragraph and the legal standards summarized in Section 2163.02 of the M.P.E.P.. It is therefore requested that this rejection of claims 36-38 be withdrawn.

III. GROUND 3 – REJECTION OF CLAIMS 42-44 UNDER SECTION 102

The rejection of Claims 42-44 is maintained under 35 U.S.C. Section 102(e) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. (*The Flaherty et al. Patent*).

Claim 42 is directed to a method of delivering medicament to tissue while preventing medicament washout, comprising: providing a medicament delivery catheter having a tissue engaging surface with a sealing balloon; providing access to a tissue surface; advancing the catheter to the tissue surface; positioning the tissue engaging surface proximate the tissue surface; sealably engaging the tissue engaging surface to the tissue surface by inflating the sealing balloon; forming a sealed opening in the tissue surface; delivering medicament through the sealed opening in the tissue surface; and, preventing the medicament from passing between the tissue engaging surface and the tissue surface to a location outside of the sealed opening.

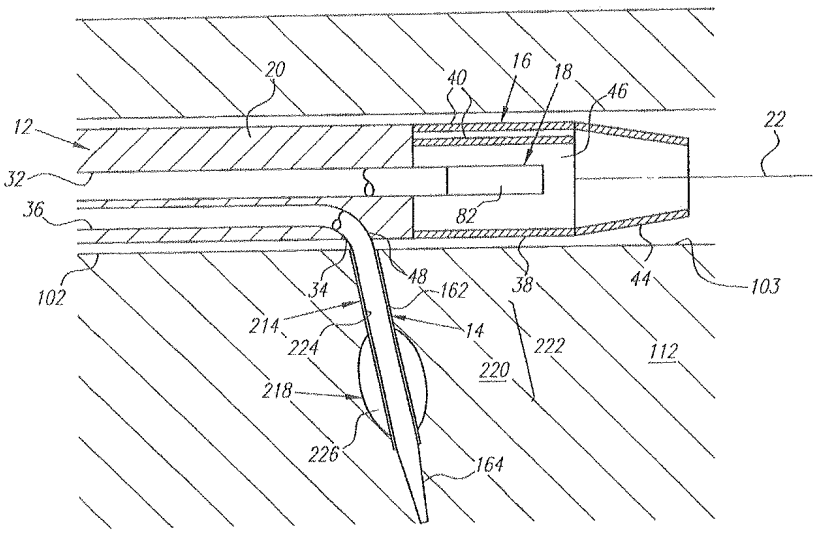

FIG. 6

As seen in Figure 6 above, *The Flaherty et al. Patent* discloses a porous drug delivery balloon 218 for infusing a drug in a predetermined pattern within the tissue 220. "The porous balloon 218 includes a porous region, such as a plurality of holes 226, a permeable membrane and the like, preferably arranged to provide a predetermined flow pattern through the balloon 218 into the tissue region 220," Col 13, lines 48-52.

In response to the Applicants arguments that *The Flaherty et al. Patent* does not show "sealing" as recited in claim 42 (see the Amendment dated March 27, 2006), the Examiner asserted in the June 30, 2006 Office Action that:

> The balloon of Flaherty et al clearly performs a sealing function, as it pushes against the tissue to distend it. Thus it is unclear how applicant can assert that the balloon does not seal the tissue when pressure is applied thereto by the balloon from maintaining pressure. The mere fact that medicament can leak out slowly does not prevent the balloon from maintaining pressure.

In response to the Applicants further arguments that *The Flaherty et al. Patent* does not show "sealing" as recited in claim 42 (see the Amendment dated November 30, 2006), the Examiner asserted in the February 22, 2007 Office Action that *The*

Flaherty et al. Patent "...expressly teaches that the balloon need not be porous (see column 2, lines 11-18). Thus the balloon of Flaherty et al clearly seals the passage."

Column 2, lines 11-14 of *The Flaherty et al. Patent* states:

> As an alternative to perfusion balloons and/or infusion catheters, a drug may be embedded in or deposited on a catheter, e.g. in the catheter wall, the wall of a non-porous balloon on the catheter, and/or a coating on the catheter.

The Examiner implies that this statement means that *The Flaherty et al. Patent* is stating that the porous drug delivery balloon 218 may alternately be non-porous. However, this implicit assertion is misleading because the "non-porous" statement of column 2 is located in the Background section of *The Flaherty et al. Patent* and is referring to drug delivery methods known in the art. Thus, in the context of the Background, this citation states that the deliver of drugs imbedded in the wall of a non-porous balloon is known in the prior art. Therefore, *The Flaherty et al. Patent* does not disclose that the porous drug delivery balloon 218 can be non-porous.

Further, in the June 30, 2006 Office Action the Examiner acknowledges that medicament can "leak out" from a tissue opening of the *Flaherty et al.* device by way of the porous drug delivery balloon 218 but incongruously argues that the porous balloon can somehow seal an opening despite these holes. This assertion ignores the meaning of the word "sealably" as used in claim 42.

For example, a common definition of "seal" according to the 2006 Encarta World English Dictionary is, "a tight closure that prevents the entrance or escape of, e.g. air or water, or a substance or device that forms such a closure." While this exemplary definition is not meant to be limiting, it does emphasize the importance of preventing entrance or escape of a substance. In contrast, the *Flaherty et al.* device is specifically intended to encourage the escape or passage of medicament through the porous balloon, thereby preventing the *Flaherty et al.* porous balloon from sealably engaging a tissue engaging surface to the tissue surface. Thus, *The Flaherty et al. Patent* does not disclose sealably engaging the tissue as recited in claim 42.

Further, even if the porous balloon of the *Flaherty et al.* device could somehow be considered to seal, it does not prevent the medicament from passing between the tissue engaging surface and the tissue surface to a location outside of the sealed opening as recited in claim 42. As previously discussed, the porous drug delivery balloon 218 encourages the escape or passage of medicament through the holes or pores in the balloon's surface.

Thus, for at least these reasons, it is requested that the Section 102(e) rejection against claim 42 be withdrawn.

Turning to claim 43, this claim depends from claim 42 and is further directed to maintaining the inflated balloon against the tissue surface while the opening is formed.

The Flaherty et al. Patent uses a puncturing element 14 (seen in Figure 6) to puncture the tissue 220. The drug delivery catheter 214 may be deployed over the puncturing element 14 and finally the porous drug delivery balloon 218 can be inflated with drugs. In other words, the opening in *The Flaherty et al. Patent* is formed first, then the drug delivery catheter 214 is positioned and finally the porous drug delivery balloon 218 is inflated with drugs. Thus, *The Flaherty et al. Patent* does not disclose maintaining the inflated balloon against the tissue surface while the opening is formed. Thus, for at least these reasons and the reasons set forth for claim 42, it is requested that the Section 102(e) rejection against claim 43 be withdrawn.

Turning to claim 44, this claim depends from claim 42 and further includes that the inflated balloon is maintained against the tissue opening while the medicament is delivered. However, *The Flaherty et al. Patent* (e.g., Fig. 6) only discloses inflating the porous drug delivery balloon within the channel created by the puncturing element 14, not against the tissue opening. Since the porous drug delivery balloon is delivering drugs, it is desirable for it to be positioned deep within the tissue to similarly deliver drugs deep within the tissue. In contrast, it is desirable for the present invention as recited in claim 44 to seal the tissue opening to allow drugs to enter and remain in the tissue while preventing medicament washout. Thus, for at least these reasons and the

reasons set forth for claim 42, it is requested that the Section 102(e) rejection against claim 43 be withdrawn.

IV. GROUND 4 – REJECTION OF CLAIMS 36-38 UNDER SECTION 103

Claims 36-38 are rejected under 35 U.S.C. Section 103(a) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. (*The Flaherty et al. Patent*) in combination with U.S. Patent No. 6,645,199 to Jenkins et al. (*The Jenkins et al. Patent*), U.S. Patent No. 6,161,543 to Cox et al. (*The Cox et al. Patent*) and U.S. Patent Application No. 2001/0049497 to Kalloo et al. (*The Kalloo et al. Publication*).

Claim 36 is directed to a method of delivering medicament to tissue in a chamber of the heart while traversing a right atrium and sealably traversing an atrial septum, comprising: introducing a medicament delivery catheter though an endoluminal entry point and advancing the catheter through a circulatory system; directing the catheter to traverse the right atrium and puncture the atrial septum of a patient to form an opening; supportively engaging the atrial septum at the opening with the medicament delivery catheter; sealing the opening with the medicament delivery catheter; further advancing the medicament delivery catheter through the sealed opening to a surface on the chamber of the heart; and creating a channel through the surface of the heart chamber and delivering medicament into the channel.

The combined references as asserted by the Examiner do not show or render obvious the present invention as recited in claims 36-38. For example, *The Flaherty et al. Patent* does not teach supportively engaging the atrial septum at an opening with the medicament delivery catheter and sealing the opening with the medicament delivery catheter.

To remedy this deficiency, the Examiner asserts that "Cox et al teach the use of means to seal the tissue around an internal chamber ablation device to prevent bleeding when working on a bleeding heart." However, as seen in column 27, lines 9-21 of *The Cox et al. Patent,* the "means to seal" is performed with sutures, staples or a clamp (i.e., devices distinct from the catheter and which are not delivered by the

catheter). In other words, the sealing taught in *The Cox et al. Patent* requires additional tools and distinct devices which are not integrated into a single method as in the presently claimed invention. Thus, contrary to the Examiner's assertion, *The Cox et al. Patent* does not show supportively engaging the atrial septum at an opening with the medicament delivery catheter and sealing the opening with the medicament delivery catheter as claimed.

Nor does The Kalloo et al. Publication make up for this deficiency. The Examiner asserts that "Kalloo et al teach the use of a dual balloon stabilizing means to aid in the placement of a surgical device." However, simply combining the balloons of *The Kalloo et al. Publication* will not achieve the invention as recited in claim 36. The device of *The Kalloo et al. Publication* is directed to performing a procedure within a stomach with an endoscope (transgastric peritoneoscopy).

While the device of *The Kalloo et al. Publication* may include balloons, these balloons are not appropriate for use with the present invention as claimed. For example, the *Kalloo* balloons are sized and configured for use on an endoscope during entry into a stomach and therefore include a relatively large diameter, large thickness and greater distance between both balloons. Simply placing these *Kalloo* balloons on a device appropriately sized for a cardiac procedure as the Examiner suggests will not result in a device that can engage and seal an atrial septum as claimed in claim 36 without some additional teaching as to how such an adaptation may be performed. The atrial septum is small and relatively delicate, requiring different design considerations than the larger and more rugged entry into the stomach.

Nor does the *The Jenkins et al. Patent* make up for this deficiency. *The Jenkins et al. Patent* is directed to a method of pushing an electrode loop with an expandable structure to create a circumferential lesion to treat atrial fibrillation. While *The Jenkins et al. Patent* may suggest a maize technique for ablating a portion of the heart, it does not make up for the deficiencies of *The Flaherty et al. Patent* since it does not teach supportively engaging the atrial septum at an opening with the medicament delivery

catheter and sealing the opening with the medicament delivery catheter. In this respect, *The Jenkins et al. Patent* fails to teach any type of sealing device and therefore does not make up for the deficiency of *The Flaherty et al. Patent* and *The Mueller Patent.*

Hence it is clear that *The Jenkins et al. Patent*, *The Cox et al. Patent* and *The Kalloo et al. Publication* do not make up for the deficiencies of *The Flaherty et al. Patent.* Accordingly it is submitted that the rejection of claims 36-38 should be withdrawn.

V. GROUND 5 – REJECTION OF CLAIMS 39 AND 40 UNDER SECTION 103

Claims 39 and 40 are rejected under 35 U.S.C. Section 103(a) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. (*The Flaherty et al. Patent*) in combination with U.S. Patent No. 6,645,199 to Jenkins et al. (*The Jenkins et al. Patent*), U.S. Patent No. 5,725,523 to Mueller (*The Mueller Patent)*.

Claim 39 is directed to a method of delivering medicament to tissue while preventing medicament washout, comprising: providing a medicament delivery catheter having a tissue engaging surface with at least one vacuum operated tissue stabilizer port; providing access to a tissue surface; advancing the catheter to the tissue surface; positioning the tissue engaging surface proximate the tissue surface; sealably engaging the tissue engaging surface to the tissue surface by activating a vacuum force through the tissue stabilizer port; forming a sealed opening in the tissue surface; delivering medicament through the sealed opening in the tissue surface; and preventing the medicament from passing between the tissue engaging surface and the tissue surface to a location outside the sealed opening.

Claim 40 depends on claim 39 and further recites that the catheter comprises at least one vacuum port positioned radially about the tissue engaging surface and at least one vacuum lumen located within the catheter.

The combination of *The Flaherty et al. Patent* with *The Jenkins et al. Patent* and *The Mueller Patent* cannot be properly relied upon to reject claims 39 and 40. For example, *The Flaherty et al. Patent* fails to show preventing the medicament from passing between the tissue engaging surface and the tissue surface to a location outside the sealed opening.

The Jenkins et al. Patent and *The Mueller Patent* do not make up for this deficiency in *The Flaherty et al. Patent*. For example, *The Mueller Patent* is directed to a device which creates a seal against an area of tissue by providing suction or a vacuum. This suction, when combined with *The Flaherty et al. Patent* would likely cause the medicament within the porous balloon to be drawn out and sucked up by the vacuum, reducing the pressure in the porous balloon and preventing the creation of a seal. Thus, medicament may pass between the balloon and the tissue surface.

In another example, *The Jenkins et al. Patent* is directed to a method of pushing an electrode loop with an expandable structure to create a circumferential lesion to treat atrial fibrillation. In this respect, *The Jenkins et al. Patent* fails to teach any type of sealing device and therefore does not make up for the deficiency of *The Flaherty et al. Patent* and *The Mueller Patent*. Hence, again it is shown that the rejection of claims 39 40 based on the combination of *The Flaherty et al. Patent* with *The Jenkins et al. Patent* and *The Mueller Patent* should be withdrawn.

VI. GROUND 5 – REJECTION OF CLAIM 41 UNDER SECTION 103

Claim 41 is rejected under 35 U.S.C. Section 103(a) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. (*The Flaherty et al. Patent*) in combination with U.S. Patent No. 6,645,199 to Jenkins et al. (*The Jenkins et al. Patent*), U.S. Patent No. 5,725,523 to Mueller (*The Mueller Patent)* in further view of U.S. Patent No. 5,607,421 to Jeevanandam et al. (*The Jeevanandam et al. Patent*).

Claim 41 depends from claim 40 and further comprises four vacuum ports positioned on the tissue engaging surface. The Examiner asserts a similar rejection as set forth in Ground 4, and further cites the *The Jeevanandam et al. Patent* as teaching

multiple vacuum ports. The arguments presented with regard to claims 39 and 40 in Ground 4 are equally applicable to claim 41. Further, *The Jeevanandam et al. Patent* does not teach multiple vacuum ports as asserted by the examiner. As seen in column 5 lines 5-10 of *The Jeevanandam et al. Patent,* the device includes three suction cups 44 to stabilize the device:

> As shown in FIG. 2B the insertable end 24 of the device has gripping means extending therefrom in the form of three suction cups 44. These cups 44 provide a means to removably mount and stabilize the insertable end 24 to the inner ventricular wall, and serve as a tripod for the end 24, and the fiber end 32.

Suction cups are often concave structures that adhere to a surface. In contrast, the vacuum ports recited in claim 41 are connect to a vacuum source, allowing a user to selectively create or disperse a vacuum at the end of the ports. Thus, *The Jeevanandam et al. Patent* does not disclose four vacuum ports positioned on the tissue engaging surface as asserted by the Examiner. For at least these reasons it is believe the Section 103 rejection of claim 41 should be withdrawn.

IV. CONCLUSION

For at least all the reasons stated herein, it is submitted that the Examiner's rejection is erroneous. As a result, the Applicant's seek a reversal of the Examiner's rejection on this appeal. Reversal is hereby affirmatively requested.

Respectfully submitted,

Dated: Date

_____
Name
Registration No. xxxxxxx

COMPANY NAME
Address

Customer No. xxxxxx

CLAIMS APPENDIX

1-35. (Canceled)

36. (Previously Presented) A method of delivering medicament to tissue in a chamber of the heart while traversing a right atrium and sealably traversing an atrial septum, comprising:

introducing a medicament delivery catheter though an endoluminal entry point and advancing the catheter through a circulatory system;

directing the catheter to traverse the right atrium and puncture the atrial septum of a patient to form an opening;

supportively engaging the atrial septum at the opening with the medicament delivery catheter;

sealing the opening with the medicament delivery catheter;

further advancing the medicament delivery catheter through the sealed opening to a surface on the chamber of the heart; and

creating a channel through the surface of the heart chamber and delivering medicament into the channel.

37. (Previously Presented) The method of claim 36 wherein the catheter comprises a first balloon and a second balloon and supportively engaging the atrial septum at the opening with the medicament delivery catheter comprises inflating a first balloon of the catheter on a proximal side of the opening and inflating a second balloon of the catheter on a distal side of the opening.

38. (Original) The method of claim 37 wherein the atrial septum is received between the first balloon and the second balloon and supported by the inflated first balloon and second balloon.

39. (Previously Presented) A method of delivering medicament to tissue while preventing medicament washout, comprising:

providing a medicament delivery catheter having a tissue engaging surface with at least one vacuum operated tissue stabilizer port;

providing access to a tissue surface;

advancing the catheter to the tissue surface;

positioning the tissue engaging surface proximate the tissue surface;

sealably engaging the tissue engaging surface to the tissue surface by activating a vacuum force through the tissue stabilizer port;

forming a sealed opening in the tissue surface;

delivering medicament through the sealed opening in the tissue surface; and

preventing the medicament from passing between the tissue engaging surface and the tissue surface to a location outside the sealed opening.

40. (Original) The method of claim 39 wherein the catheter comprises at least one vacuum port positioned radially about the tissue engaging surface and at least one vacuum lumen located within the catheter.

41. (Original) The method of claim 40 wherein the catheter comprises four vacuum ports positioned on the tissue engaging surface.

42. (Previously Presented) A method of delivering medicament to tissue while preventing medicament washout, comprising:

providing a medicament delivery catheter having a tissue engaging surface with a sealing balloon;

providing access to a tissue surface;

advancing the catheter to the tissue surface;

positioning the tissue engaging surface proximate the tissue surface;

sealably engaging the tissue engaging surface to the tissue surface by inflating the sealing balloon;

forming a sealed opening in the tissue surface;

delivering medicament through the sealed opening in the tissue surface; and,

preventing the medicament from passing between the tissue engaging surface and the tissue surface to a location outside of the sealed opening.

43. (Original) The method of claim 42 wherein forming a sealed opening in the tissue surface comprises maintaining the inflated balloon against the tissue surface while the opening is formed.

44. (Original) The method of claim 42 wherein the inflated balloon is maintained against the tissue opening while the medicament is delivered.

45. (Canceled)

EVIDENCE APPENDIX

It is believed that no evidence has been presented or relied on from §§ 1.130, 1.131, or 1.132 of MPEP § 41.37 or of any other evidence entered by the examiner.

RELATED PROCEEDINGS APPENDIX

It is believed that there are no proceedings related to the present Application.

Respectfully submitted,

Date: December 21, 2007

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